

SPL ER/DL Team

Feb 2, 2011

Minutes

NEW Teleconference information:

USA Toll-Free 866-213-2145

Access code: 273 8216

Chair for this meeting: Jessica Dunn-Skorupski

1. Removing product SPL files from DailyMed if the NDA and/or NDCs have been withdrawn – Jackie
 - a. NLM sent back an error saying that the NDAs and/or NDCs were withdrawn.
 - b. Problem is that ANDA has already been withdrawn. There is notice in the Federal Register. Not recognizing the product. Reporting an NDA/NDC that isn't being recognized.
 - c. This could be an exception – send note to DLRS staff and cc: SPL describing the situation. The SPL file would need to be overridden to get it through the validation system. DRLS staff won't be able to override any situation, so Lonnie will need to be involved. Also reference the Federal Register notice acknowledging the outcome.
 - d. Jackie will let us know what happens.
2. We have a product SPL file still posted on DailyMed. As we were converting the file from the R3 to R4 we realized we have 4 NDCs all under the same product code, yet 2 ANDAs for that product code. Our experience is that you can only have one NDA/ANDA/BLA per product code in the SPL file and we're not sure how to approach this filing. – Jackie
 - a. Terry, per Lonnie. Just list one of the 2 ANDA numbers. The NDA number is not crucial for the listing process.
 - b. The formal withdrawal of the ANDA needs to be done through the review division.
3. Is anyone using their SPL documents in place of Web PI's for search engines such as Google? – Herb
 - a. Google is now turning down pdf files when you do a google search. They are sending the SPL files to google and it is not working.
 - b. Has anyone else heard about this. This came up at Takeda. Herb sent a file as a test, and it didn't work.
 - c. Why would we want to send it to Google? There is a control issue here. The current label is already posted to corporate web site and Daily Med.
 - d. Herb will keep us updated.
4. SPL documents with a change to the section's effective time value but no change to the section ID will receive the following error: "id does not match any other id across all sections, documents, or any id other than the id of the same section previously submitted." This is the first time I have received an error like this and I would like to get some more information from the group. – Kathi
 - a. 2 SPLs that both have the same product code with different package types.
 - b. Check your SPLs within your file. The GUIDs might have been reused between documents – ie all the GUIDs between the 2 SPLs must all be different. The validation will check to make sure that all the GUIDs are unique across all documents.
 - c. Even the generic manufacturers must change all their GUIDs from the reference label.
 - d. Many software tools will change the GUIDs automatically.
 - e. Section GUID and effective time should change. The section ID is an internal number

5. CMS and smallest dispensable unit – Jackie
 - a. Request from FDB asking why the smallest dispensable unit wasn't listed in the SPL—even though it isn't a "sale-able" unit.
 - b. Several companies have had similar requests for NDC codes for "single" billable units...coming in from CMS. CMS have been creating NDC codes when an NDC code doesn't exist.
 - c. Tom Bizarro from FDB has been invited to come to our ER/DL session to explain how NDC codes are used for reimbursements by Medicare/Medicaid.
 - d. We have been asked to drug list down to the lowest "sale-able" unit. FDA has to be on board of how NDCs should be used. If other downstream users are creating their own NDCs, then sponsors shouldn't be asked to drug list down to the billable unit.
 - e. Terry has asked Lonnie about this.

6. Observations on updated SPL Stylesheet – Pat
 - a. Stylesheet changes:
 - i. New text on NDC numbers "NDC:"
 - ii. New text in description: "100 blisterpacks (100 blisterpacks) in 1 carton"
 - b. Displaying the stylesheet in IE.
 - i. Background shows up as red when you print to Adobe or do a print preview.
 - ii. Mary Beth had the same issue.